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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,419	08/29/2005	Claude R Mallet	60008US(49991)	4959

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EXAMINER	
GITOMER, RALPH J	

ART UNIT	PAPER NUMBER
1657	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,419	MALLET ET AL.	
	Examiner	Art Unit	
	Ralph Gitomer	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,3-5,10,12-16 and 52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,10,12-16 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The amendment received 9/7/10 has been entered and claims 1, 3-5, 10, 12-16, 52 are currently pending in this application. A single species of surfactant has been elected as applied to method claims 1, 3-5, 10, 12-16, 52 as seen on page 14 of the specification, however no claim is limited to the elected specie. And the elected specie directed to a compound is not a novel compound.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-5, 10, 12-16, 52 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 13-20 of U.S. Patent No. 7,229,539. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '539 are more specifically drawn to electrophoresis and the present claims are more generally directed to analysis.

Applicant's arguments filed 9/7/10 have been fully considered but they are not persuasive.

Applicants response argues that upon allowable matter being found, the above rejection will be further considered.

The invention as described in the specification is directed to analysis of a small molecule obtained by lysis of cells with a surfactant where the surfactant is removed prior to mass spec analysis. The improvement is using a specific surfactant with similar properties to SDS but degrades in acid and thereby can be readily removed. The specification defines small molecule on page 6 first paragraph as all molecules with an atomic mass of less than about 1000. The claims have now been amended where the analyte is a non-proteinaceous small molecule which is not a peptide.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-5, 10, 12-16, 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Lee in view of Schneider.

Lee (WO 00/70334 A1) entitled "Destructible Surfactants and Uses Thereof" teaches on page 1 methods for analysis of large molecules such as proteins and peptides with surfactants that can be destroyed at low pH levels. On page 5 lines 15-18 the surfactants may be used in applications which benefit from the initial presence and ultimate removal of a surfactant such as volatilization, analysis, separation, purification and/or characterization of large molecules. On page 12 the same compound as presently elected is disclosed. See the claims which simply refer to a sample and do not refer to its molecular weight.

The claims differ from Lee in that they specify the method is for analysis of a non-proteinaceous small molecule which is not a peptide where the references refer to large molecules.

Schneider (US 2005/0153346) entitled "Methods for Conducting Metabolic Analyses" teaches in paragraph 125, mass spectrometry can be used according to known methods to determine the masses of relatively small molecules as well as relatively large molecules. MALDI is among the most commonly used mass spectrometric techniques.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the surfactant taught by Lee who analyzes large molecules to then analyze non-proteinaceous small molecules because the surfactant of Lee would have the same function irrespective of the type of analyte. Lee shows that it is desirable to use the presently elected surfactant as compared to SDS to improve the analysis of the digests. So to begin with small molecules and analyze them would

be a subset of the analysis taught by Lee who analyzes the products of large molecules which are then reacted to form small molecules which are analyzed. Schneider teaches mass spec can be used to determine both large and small molecules. No novelty is seen in the selection of a known surfactant employed for its known function with the expected result in the method of Lee applied to any analyte such as those shown by Schneider who also employs the same analytical methodology of Lee but employs more common surfactants. Further, one would expect in general it is harder to analyze large and/or proteinaceous analytes than it is to analyze small and non-proteinaceous analytes.

One would have a high expectation of success in employing a method known to analyze small peptides and then analyze non-proteinaceous small molecules by the same method for the same purpose. The point of novelty appears to be the substitution of SDS with the presently elected acid degradable surfactant and this substitution is clearly taught by Lee for the same function as claimed.

Applicant's arguments filed 9/7/10 have been fully considered but they are not persuasive.

Applicants response argues that Lee does not teach the analysis of digests of non-proteinaceous small molecules that are not peptides but specifically proteins or peptides. Further neither Lee or Schneider teach dissociation of the small molecule from the protein binding effect. Schneider describes MALDI for analysis of different sized molecules where proteinaceous large molecules are ionized by MALDI and not

digested into non-proteinaceous small molecular species. There is no teaching that MALDI analysis of a peptide or protein would result in the creation of a small molecule digest rather than merely ionize the sample. Use of the presently claimed surfactant has a surprising and unexpected result of releasing a small molecule form a biological sample for analysis where it avoids protein binding of small molecules which are associated with other surfactants such as SDS which permits more complete recovery of small molecules in total, free form and bound form.

It is the examiner's position that Lee states on page 1 lines 1-2, methods for analysis of large molecules such as proteins or peptides are described employing the same surfactants as presently claimed for the same function. On page 6 line 32 MALDI is an example of mass spec described where MALDI can digest the sample whereby large molecules are reacted to produce small molecules and the small molecules are determined. It would then be likely proteins would be digested into peptides and amino acids for further analysis and to do so, they would be dissociated. There are several functions of MALDI and the method is commonly employed where digesting large molecules is desired. The surfactant employed by Lee is the same surfactant as presently claimed and would inherently have the same function. No advantages or features of employing the elected surfactant are claimed. Schneider teaches on page 12 paragraphs 124-125, 128, some of the many types of molecules that can be analyzed with mass spec including relatively small molecules as well as relatively large molecules. Labeled carbon dioxide can also be detected using mass spec. The samples would be dissociated within the mass spec and therefor isolated.

Regarding the references presented, it is understood that different classes of compounds lend themselves to different types of analysis. To then consider all compounds as either small or large and generalize analytical methods from there would not apply in many instances. The present invention lies in the selection of a surfactant with a known function and a feature of being functionally inactivated by acid. Many analytical methods employ surfactants for both large and small molecules and selecting any known surfactant in a method which is known to employ surfactants with the expected result would have been obvious. No novelty is seen in the function of the elected surfactant, the analyte or in the claimed analytical method. And the elected surfactant is not a novel compound.

Regarding the newly added feature of the sample not being a peptide, in the present specification in paragraph 31 the sample may include proteins and peptides.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

“The analysis further characterization" lacks antecedent basis and is unclear.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/
Primary Examiner, Art Unit 1657

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